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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,548	09/15/2006	Andrea Heger	P71281US0	5978

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,548	HEGER ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-24* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 12-22, 24 are pending and are considered on the merits. Claim 23 has been withdrawn. Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original "use" claim 10 was directed to the "use" of the composition of claim 1 to make a medicament. "Use of the blood plasma of claim 1 for the manufacturing of a medicament for the treatment of...". New claim 23 now claims the "use" of the composition to treat a disease state. Thus, this is an independent invention because the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used to treat hypovolemic shock.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 12-22, 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-28 of copending Application No. 12/222,457. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 12-22, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The definition of Caucasian according to the Random House Dictionary [U] is a person with fair to dark skin, straight to tightly curled hair and light to very dark eyes inhabiting Europe, parts of North Africa, Western Asia and India. Caucasian in its alternate definition relates to the inhabitants around the Caucasus mountains, i.e. Georgians, Abkhazians, Avars, etc. who speak languages that belong to the Caucasian language family. Thus, the definition of Caucasian is a varying one, sometimes it means “white people” which does not include the "yellow races", into which Asians are sometimes classified. It is not a modern scientific term, but is more of a political term with varying definitions according to political desires. Races delineations promoted by Carleton Coon in 1962 used such terms as Caucasoid, Mongoloid, Australoid, Negroid and thus places Asians into a different classification from Caucasoid, which is in conflict with the previous dictionary definition of Caucasian.

The term “non-Caucasian population” is indefinite because it is a definition which requires a person to be either Caucasian or not. There are no gradations of categorization. For example, is a person born of a native Kenyan father and an Irish mother a non-Caucasian or a Caucasian, since that person has inherited half European and half African DNA from parents with these geographical origins. Which half will be the dominating classification, surely this is arbitrary. Also, the “Hispanic” classification includes people whose geographical origins are European as well as African. Are all Hispanics then non-Caucasian, even though they may have, for example, Incan, Spanish or even Jewish ethnic or geographical origins?

Caucasian and its inverse, non-Caucasian are terms which are not scientifically accurate according to present-day knowledge and therefore have

no precise and agreed upon definitions and which have no set metes and bounds and are therefore, indefinite.

If applicants wish to identify a plasma with certain characteristics, they should use scientifically unambiguous terminology, such as concentrations of markers.

NEW MATTER

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 22 recites "a transfusion unit dose" which has no support in the original claims or in the specification as filed.

Claim 24 recites "A packaged unit" which has no support in the original claims or in the specification as filed.

Insertion of these limitations have no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Claim Rejections - 35 USC § 103

Claims 12-14, 19-22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/07390 [IDS] in view of Aubert *et al.* [V].

The claims are directed to a plasma composition comprising:
5-6 parts plasma from type A donors,
4-5 parts plasma from type B donors,
0-1 parts plasma from type AB donors
0 parts plasma from type O donors.

Therefore, simple calculation determines that the ranges in the claim allow (rounded off),

45-60% of the plasma to be from type A donors,
36-50% of the plasma to be from type B donors,
0-10% of the plasma to be from type AB donors,
with no plasma from type O donors.

Dependent claims require the titer for anti-A and anti-B IgM to be lower than 16 and for anti-A and anti-B IgG to be lower than 64.

The references are relied upon as explained below.

WO 99/07390 teach a plasma composition comprising:
6-10 parts plasma from type A donors,
1-3 parts plasma from type B donors,
0-1.5 parts plasma from type AB donors,2
0 parts plasma from type O donors page 2.
Therefore, by calculation,

57 to 91% plasma from type A donors,
8 to 33% plasma from type B donors,

0 to 17% plasma from type AB donors,
0 parts plasma from type O donors.

The plasma has a titer of lower than 16 for anti-A and anti-B IgM, and lower than 64 for anti-A and anti-B IgG (page 4).

Detergent/solvent virus inactivation processes are also taught as well as frozen, lyophilized, fresh liquid forms (page 3).

Although the reference does not state that the plasma is packaged in unit dosage form, the reference on page 3, states that the blood plasma can be stored and delivered in any state known to the skilled person. This is interpreted to be unit dosage forms and prepackaged forms. Please remember that a determination of obviousness is distinct from a determination of new matter.

Aubert *et al.* teach the principle of neutralization of plasma or serum by making the agglutinogen and iso-agglutin contents of the plasma neutralize each other by pooling suitable amounts of plasma or whole blood from different blood groups and measuring the resultant titer (page 102). This is the theoretical construct of the instant invention.

With regard to the differences in concentrations between the instant claims and the disclosure of the prior art, see MPEP 2144.05 I. and II.

Generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation, *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

One of skill in the art is fully capable of mixing plasmas from different

blood group donors in a fashion so as to reduce the anti-A, anti-B IgG and IgA titers to any level desired, particularly since there are standard tests for these antibodies and Aubert *et al.* has taught the basic principles involved. The crux of the invention is to produce a plasma with negligible iso-agglutinin titers for transfusion purposes. Whether the plasma is obtained from populations which are termed "non-Caucasian" or not is of little patentable weight particularly since that term is ambiguous. It is the titer of the antibodies in the plasma which is critical not the skin color of the human from which it is derived.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/07390 [IDS], Aubert *et al.* [V] as applied to claims 12-14, 19-22, 24 above, and further in view of US 2003/0133829 [A].

The claims are further directed to the use of various chemicals to inactivate virus in plasma.

US 2003/0133829 in the Background of the Invention [0003-0012], describes known processes which employ solvent and detergents such as Triton and fatty acids such as caprylic acid to inactivate virus in biological products such as plasma.

The employment of any known process to inactivate virus in the process of producing a universal plasma taught by WO 99/07390 would have been obvious when taken with US 2003/0133829 which describes such viral inactivation processes, particularly because WO 99/07390 invites the use of any known viral inactivation process on page 3.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 12/16/09 have been fully considered but they are not persuasive.

Applicant argues that non-Caucasian and Caucasian are well known and accepted nomenclature in the scientific/medical community. This is not persuasive as the term has little scientific standing, see Britannica Concise Encyclopedia [U].

Interestingly, the definition (2) supplied by applicant from MedlinePlus is a legal one, i.e. related to the white race as DEFINED BY LAW.... What may be a legal definition of Caucasian and non-Caucasian in South Africa or Germany or Europe may not the same as in the United States, for example. Applicant has merely confirmed the various conflicting definitions which are based not in biological sciences but in law and social usage, which varies from time to time and place to place.

Definition (1) supplied by applicant refers to the white race. Jews, for example were once defined as non-white, and have now been reclassified, see page 43, "The Meanings of Race", Lee *et al*. [V]. Race is not a proper scientific term and is therefore indefinite because of its changing meanings. With regard to the arguments that papers have been published that use the terms Caucasian and non-Caucasoid, see pages 53-54, “Race in Health Research”, Lee *et al*. [V] where it is stated that there is a lack of consistency for the use of terminology for concepts of race in the literature and it continues to be used erroneously as a scientific variable.

In short, Caucasian and non-Caucasian are not clearly defined scientific terms and are subject to change depending on social environments that is, it means different things to different people in different countries at different times.

Applicant argues that the “use” claim 10 is entitled to examination on the

merits. Please note in the previous action claim 10 was examined on the merits and the process for manufacturing the product was been found to be obvious over the references of record. Use claims have been found to be improper process claims in US Patent practice, see *Ex parte Duni*, 153 USPQ 678 (Bd. App. 1967*), Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ (D.D.C. 1996). Also see MPEP 2173.05(q).

Applicant argues that all claim limitations must be taught or suggested by the prior art and applicant urges that donors of a non-Caucasian population are not taught by the cited reference. First, the cited reference is not limited to certain donor "races", and thus can be interpreted to encompasses all donors. Second, note that the claims are directed to a composition. Blood or plasma has no "race" if "race" exists at all. If the composition is obvious over the composition taught by the cited reference, then it is of little import, in a product by process claim, how the composition is made, see *In re Marosi* 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe* 227 USPQ 964 (Fed. Cir. 1985), and MPEP 2113. The composition claimed is obvious of the cited prior art because it has similar characteristics in terms of blood group characteristics and for reasons of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651